

4/24/00

Washington State Medical Test Site Rules
PRE-INSPECTION SELF-ASSESSMENT CHECKLIST

MICROSCOPIC EXAMINATIONS

Wet mounts (vaginal, cervical, skin or fecal specimens); KOH preps; pinworm preps; Fern test; post-coital direct exams; urine sediment; nasal smear for granulocytes; and post vasectomy qualitative semen analysis.

TEST COMPLEXITY:

PPMP (Provider-Performed Microscopic Procedures)

When the microscopic tests listed above are performed only by a provider (MD, DO, Dentist, ARNP, Midwife, PA, Naturopath, Podiatrist) and in conjunction with the patient's visit, the tests are categorized as PPMP. Labs licensed as PPMP must adhere to all applicable requirements for moderate complexity testing, but are not subject to routine on-site inspections.

MODERATE

When the microscopic tests listed above are performed by personnel other than one of the listed providers, they are considered moderate complexity testing.

PROFICIENCY TESTING REQUIREMENTS:

Not required, but must perform biannual verification of accuracy for these tests. Some proficiency testing programs are available for these tests and can be used for the biannual verification of accuracy.

The following requirements apply to both PPMP and Moderate complexity microscopic procedures:

PERSONNEL

- ___ The director, supervisor and testing personnel meet personnel qualifications for moderate or high complexity testing [42 CFR Part 493 subpart M (CLIA) - Available from the LQA Office]
- ___ Documentation of personnel education, experience, training for the testing performed
- ___ Annual documentation of the assessment of personnel competency
- ___ Training is provided to personnel when problems are identified
- ___ Laboratory safety policies are written and staff adhere to them

QUALITY CONTROL

- ___ Procedures are written which include: specimen collection and handling; preparation of reagents and stains; preparation and examination of slides; interpretation of results; reporting protocol; quality control; quality assurance
- ___ Have available reference books, atlases to aid in the identification of unknowns
- ___ Reagents are properly labeled, stored and used within expiration date
- ___ Microscope, centrifuge maintenance is performed and recorded

MICROSCOPIC EXAMINATIONS CHECKLIST

page 2

QUALITY ASSURANCE

- ___ Policies are written and there is evidence of review of quality control, quality assurance, proficiency testing (or biannual verification of accuracy) and patient test results
- ___ Evidence of correlation of microscopic exam results with clinical findings or other lab test results (where possible) - i.e., correlation of urine sediment exam results versus results of urine dipstick or urine culture
- ___ Policies are written regarding specimen acceptance/rejection
- ___ Policies are written defining critical values (as applicable)
- ___ Documentation of corrective actions when problems are identified
- ___ Assure that adequate space and facilities are available
- ___ Adhere to local, state and federal regulations for hazardous waste disposal

RECORDKEEPING

- ___ Patient test orders include: patient name or identifier; person ordering the test; date and time of specimen collection; patient age and sex (if appropriate)
- ___ Patient test reports include: name and address of where tests were performed; patient name or identifier; date specimen received; date reported; normal ranges; specimen limitations
- ___ Records are kept for 2 years of lot numbers and expiration dates of reagents and stains and dates when placed into use
- ___ The following records are maintained for 2 years: Requisitions; test records; reports; quality control; quality assurance; proficiency testing; and biannual verification of accuracy data